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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/463,874 | 06/07/2000 | ERICH WANKER | V0179/7000 | 6909 |

7590 08/31/2005

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EXAMINER

CHERNYSHEV, OLGA N

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1649

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/463,874 | Applicant(s) WANKER ET AL. | |
| | Examiner Olga N. Chernyshev | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-11 and 24-29 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 9 and 10 is/are allowed.
- 6) ☒ Claim(s) 11 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claims 1, 2 and 11 have been amended, claims 5 and 8 have been canceled and claims 24-29 have been added as requested in the amendment filed on July 25, 2005. Following the amendment, claims 1-4, 9-11 and 24-29 are pending in the instant application.

Claims 1-4, 9-11 and 24-29 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on July 25, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. Claims 11 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition as recited in claim 1 does not reasonably provide enablement for a composition comprising a host cell derived from transgenic animals or

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plants for those reasons of records as applied to claim 11 in section 4 of Paper mailed on March 22, 2005.

Applicant submits at page 5 of the Response that “the compositions of the invention do not require one to make transgenic cells but rather to simply use the cells”. Applicant’s arguments have been fully considered but are not persuasive because claim 11, as written expressly requires the production of transgenic animals or plants based on the limitations present within the claim. One skilled in the art readily appreciates that art of production and use of transgenic animals or plants is not routine and easily predictable at present, as it was not at the time of filing of the instant application. Furthermore, the intend of using the transgenic animal or plant cells as host cells is clear from the presence of these limitations because the instant claim recites “an animal cell”, “an insect cell” and “a transgenic animal cell”, which appear to be specific embodiments encompassing “an animal cell”.

Thus, for reasons set forth in the previous office action and reasons above, the instant rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 28 is vague and indefinite in so far as it employs the term “huntingtin exon 1 protein” as a limitation. Because the instant specification does not identify that property or

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combination of properties which is unique to and, therefore, definitive of a "huntingtin exon 1 protein", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Furthermore, because the instant claims recite "huntingtin exon 1 protein" and also "huntingtin (poly)peptide" as in claim 1, for example, the metes and bounds of each limitation with respect to structure or recited proteins/(poly)peptides cannot be positively defined.

9. Claim 29 is rejected being dependent from indefinite claim.

Conclusion

10. Claims 1-4 and 9-10 are allowed. Claims 11 and 24-29 are rejected.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

August 30, 2005